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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,648	10/09/2001	Scott Daniel Hofmann	WHS-7917	9983

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LERNER AND GREENBERG, PA
P O BOX 2480
HOLLYWOOD, FL 33022-2480

EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,648	HOFMANN, SCOTT DANIEL	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-18* is/are rejected.

7)☐ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed 6/27/2003 is acknowledged and has been entered. Applicant's submission of the sequence listing in computer readable format (CFR) on 10/30/2003 is acknowledged and has been entered.

Specification

2. The disclosure is objected to because of the following informalities:

(a) The disclosure at page 6, lines 11-13, 15; page 7, lines 2, 22-23 and page 8, line 22 contains brackets not intended to encompass an amendment (see 37 CFR 1.121(e)(2)(ii)). It is suggested removing the brackets from the specification.

(b) The words "avodin" and "strepavodin" are misspelled in claim 4. It is suggested changing "avodin" to --avidin-- and "strepavodin" to --streptavidin--.

Appropriate correction is required.

(c) The article "a" is duplicated in line 4 of claim 18. It is suggested removing one of the duplicates.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 7 lacks proper antecedent basis for "the peptide antigen having a detector" because claim 6 from which it depends do not recite "a peptide antigen" but recites "a radioactive label". Clarification is required as to Applicant's intent.

Claim Rejections - 35 USC § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 7, 9, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerbes, John. (WO 97/03207, January 30, 1997). Regarding claim 1, Gerbes et al teach a method for detecting and capturing a double-stranded DNA sequence, which comprises: providing a sample, adding a forward primer for the double stranded DNA sequence and a reverse primer for the double stranded DNA sequence, one of the forward primer and the reverse primer having a capture agent, the other of the forward primer and the reverse primer having a detection agent; replicating the double-stranded DNA sequence; binding the capture agent to a capture medium; rinsing the sample, and detecting the detection agent (pages 19-21, Examples 4 and 5).

Regarding claim 2, Gerbes teaches the embodiment of claim 1, which further comprises selecting the capture agent wherein said capture agent is biotin (examples 4 and 5).

Regarding claims 3 and 9, Gerbes teaches the embodiment of claim 1, wherein said capture agent or detecting agent may include a molecule spacer (bridge or anchor molecule) to prevent the capture agent from affecting the attached primer (page 13, lines 6-10).

Regarding claim 4, Gerbes teaches the embodiment of claim 1, which further comprises a capture medium comprising streptavidin (Examples 4 and 5).

Regarding claim 5 and 7, Gerbes teaches the embodiment of claim 1, which further includes a detecting agent consisting of a peptide antigen (hapten). Gerbes further teaches wherein the method further comprises adding a monoclonal antibody specific to the peptide antigen as detector (examples 4 and 5).

Regarding 13, Gerbes teaches the embodiment of claim 1, which further comprises detecting qualitatively the presence of the double stranded DNA (page 11, lines 13-15).

Regarding claim 15, Gerbes teaches the embodiment of claim 1, wherein the replicating step comprises replicating the double stranded DNA using PCR (examples 4 and 5).

Regarding claim 16, Gerbes teaches the embodiment of claim 1, which further comprises binding the capture agent to a stationary phase (examples 4 and 5).

Regarding claim 17, Gerbes teaches the embodiment of claim 1, which further comprises binding the capture agent to a mobile phase (beads or microparticles) (example 2)

Therefore, Gerbes meets the limitations of claims 1-5, 7, 9, 13 and 15-17 of the instant invention.

Claim Rejections - 35 USC § 102(e)

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4, 5, 7, 8, 14-16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558 B1, filing date April 14, 2000, effective filing date May 18, 1997). Regarding claim 1, Henkens et al teach a method for detecting and capturing a double-stranded DNA sequence, which comprises: providing a sample, adding a forward primer for the double stranded DNA sequence and a reverse primer for the double stranded DNA sequence, one of the forward primer and the reverse primer having a capture agent, the other of the forward primer and the reverse primer having a detection agent; replicating the double-stranded DNA sequence; binding the capture agent to a capture medium; rinsing the sample, and detecting the detection agent (col. 7, lines 20-47; col. 21, line 60 to col. 22, lines 1-4 and 62, lines 50-67).

Regarding claim 2, Henkens et al teach the embodiment of claim 1, which further comprises selecting the capture agent wherein said capture agent is biotin (col. 8, lines 19-21and col. 62, lines 50-67).

Regarding claim 4, Henkens et al. teach the embodiment of claim 1, which further comprises a capture medium wherein said capture medium comprise avidin (neutrAvidin) (col. 10, lines 23-28).

Regarding claim 5 and 7, Henkens et al teach the embodiment of claim 1, which further includes a detecting agent selected from the group consisting of fluorescein or peptide antigen. Henkens et al further teach wherein the method further comprises adding a monoclonal antibody specific to the peptide antigen having a detector (col. 8, lines 22-27).

Regarding claim 8, Henkens et al teach the embodiment of claim 1, which further comprises a detector wherein said detector comprises fluorescent antibodies (col. 10, lines 23-28).

Regarding 14, Henkens et al teach the embodiment of claim 1, which further comprises detecting quantitatively the presence of the double stranded DNA (col. 1, lines 18-20).

Regarding claim 15, Henkens et al teach the embodiment of claim 1, wherein the replicating step comprises replicating the double stranded DNA using PCR (col. 62, lines 50-67).

Regarding claim 16, Henkens teaches the embodiment of claim 1, which further comprises binding the capture agent to a stationary phase (sensor) (col. 62, lines 50-67).

Regarding claim 18, Henkens et al teach a method for detecting and capturing a double-stranded DNA sequence, complementing a single stranded RNA sequence which comprises: providing a single stranded RNA sequence, adding a forward primer complementing the single stranded RNA; reverse transcripting the single stranded RNA to produce a double-stranded DNA sequence, adding a reverse primer for the double stranded DNA sequence, one of the forward primer and the reverse primer having a capture agent, the other of the forward primer and the reverse primer having a detection agent; replicating the double-stranded DNA sequence; binding the capture agent to a capture medium; rinsing the sample, and detecting the detection agent (see figure 13; col. 6, lines 3-4; col. 7, lines 20-47; col. 21, line 60 to col. 22, lines 1-4 and 62, lines 50-67). Therefore, Henkens et al meets the limitations of claims 1, 2, 4, 5, 7, 8, 14-16 and 18 of the instant invention.

9. Claims 1, 2, 4, 5, 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al (US 6,319,469 B1, filing date December 18, 1996). Regarding claims 1, Mian et al. teach a method for detecting and capturing a DNA sequence which comprise adding a forward and reverse primer for the DNA sequence, one of the primer having a capture agent and the other of the primer having a detection agent, replicating the DNA sequence, binding the capture agent to a capture medium, rising the sample and detecting the detection agent (col. 43, lines 19-59).

Regarding claim 2, Mian et al. teach the embodiment of claim 1, which further comprises a capture agent comprising biotin (col. 43, lines 26-34).

Regarding claim 4, Mian et al teach the embodiment of claim 1, which further comprises selecting the capture medium comprising streptavidin (col. 43, lines 26-43).

Regarding claim 5, Mian et al. teach the embodiment of claim 1, which further includes a detecting agent comprising of a radioactive label or fluorometric dye (col. 43, lines 26-34).

Regarding claim 10, Milan et al. teach the embodiment of claim 1, which further comprises a multiplex detection system comprising the use of multiple reaction-specific or DNA fragment-specific detectable labels (col. 43, lines 45-50).

Regarding claims 11 and 12, Mian et al. teach the embodiment of claim 1, which further comprises using a radioactive detection agent and detecting the detection agent with a radiodetector (clm 11) or using a fluorescence detection agent and detecting the detection agent with a fluorometer (clm 12) (col. 21, lines 11-48 and col. col. 25, lines 11-20). Therefore, Mian et al meet the limitations of claims 1, 2, 4, 5, 10-12 of the instant invention.

Conclusion

10. No claims are allowed. Claim 6 is objected because it depends from a rejected claim. Claim 6 has not been rejected under prior art because no prior art was found teaching or suggesting a method of detecting and capturing a double stranded DNA sequence using the radioactive label Iodine-151. No motivation could be found in the prior art for using Iodine-151 in the claimed method and accordingly an obviousness-type rejection could not be made.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Wilder

CYNTHIA WILDER
PATENT EXAMINER

6/9/2004